UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

CIVIL ACTION NO. 1:12-cv-00746 (WOB-KLL)

SHIRLEY MONROE
And WILLIAM MONROE, JR. **PLAINTIFFS**

VS. **Memorandum Opinion and Order**

NOVARTIS PHARMACEUTICALS CORP. **DEFENDANT**

This is a product liability case under Ohio law, and this Court has original subject matter jurisdiction based on diversity. Shirley Monroe, substituted plaintiff Joseph Kaufman, and William Monroe, Jr. ("Plaintiffs") allege inadequate warning, nonconformance with manufacturer's representation, design defect, and loss of consortium claims against Novartis Pharmaceutical Corporation ("Defendant"). Shirley Monroe developed osteonecrosis of the jaw ("ONJ") while taking Zometa, a drug manufactured by Defendant, giving rise to these product liability claims.

This matter is before the Court on the Defendant's motion for summary judgment as to all claims against it. (Doc. 48, Defendant's Motion for Summary Judgment). Defendant also filed motions to exclude expert witnesses. (Doc. 46, 54, 55, 56, 57). However, they are not all essential to the resolution of Defendant's Motion for Summary Judgment.[1]

[1] Professor Wayne Ray was withdrawn as an expert, thus Defendant's motion to exclude him is moot. (Doc. 55, 62).

FACTS

A. Facts relating to the merits

Mrs. Monroe was referred to Dr. Arthur Richards in 2005 after a sneeze fractured a lumbar vertebra. (Doc. 58-3 p.19, Deposition of Dr. Richards). A biopsy was conducted which showed plasmacytoma, a type of cancer. (*Id.*) Dr. Richards first saw Mrs. Monroe on May 18, 2005. (*Id.*) He first prescribed Zometa on May 25, 2005. (*Id.* at p. 23). She was prescribed four milligrams of Zometa every four weeks to be administered by IV. (*Id.* at p. 28). Mrs. Monroe's last dose of Zometa was administered on June 16, 2008. (*Id.* at p. 41). On August 11, 2008, Dr. Richards diagnosed osteonecrosis of the jaw and told her "that the osteonecrosis is partly due to Zometa and that all of the bisphosphonates have been associated with this problem." (*Id.* at p. 38). He also stopped her Zometa at this time. (*Id.*)

Dr. Richards testified that he did not remember discussing the risks of Zometa with Mrs. Monroe. (*Id.* at pp. 23-24). When asked what risks he generally discussed when prescribing Zometa, he answered "renal toxicity and headache with the infusion, and . . . I would like to think that we discussed ONJ. I would hope so. I think we probably did." (*Id.* at p. 24). Mrs. Monroe signed a consent form that she accepted the risk of certain side effects as it related to Zometa. (Doc. 48-22, Oncology/Hematology Care, Inc. Informed Consent for Treatment). This form was for treatment and did not mention ONJ, but Defendant points out it did warn about "Life Threatening complications/death." (*Id.*)

Dr. Richards's notes of September 5, 2007 state that he wanted to reduce Mrs. Monroe's dosing of Zometa to every eight weeks "because of concerns of osteonecrosis." (*Id.* at p. 32). Dr. Richards could not state with certainty if the concern was with her upcoming dental surgery or his general practice of reducing Zometa treatments because of a Mayo Clinic recommendation to reduce the frequency of administration of Zometa. (*Id.* at pp. 34-35).

Mrs. Monroe was diagnosed with ONJ and referred to Dr. Patil. (Doc. 51-9 p. 28, Deposition of Dr. Patil). He initially was concerned she had cancer in her jaw, but he ruled this out. (*Id.* at p. 29). Eventually, he performed several surgeries removing teeth, bone fragments, and later performed mandible and maxilla reconstruction surgery. (*Id.* at pp. 38-39, 55, 68-69).

Defendant emphasizes that Mrs. Monroe failed to obtain proper dental treatment prior to the discovery of her ONJ. However, there is no evidence that this impacted her development of ONJ. Instead, Plaintiffs' retained expert, Dr. Kraut, opined that unless there was some prior dental extraction shortly before she was diagnosed with ONJ, it would likely be spontaneous ONJ. (Doc. 48-23 p. 210, Deposition of Dr. Kraut).

Dr. James Vogel's expert report indicates that "the risk for developing ONJ increases with the amount of bisphosphonate a patient takes." (Doc. 54-8 ¶ 22).[2] However, Dr. Richards's affidavit states that he would still prescribe Zometa, even knowing what he knows now,

[2] Defendant filed a motion to exclude a portion of Dr. Vogel's expert report. (Doc. 54).

if Mrs. Monroe presented today exactly as she did in 2005. (Doc. 48-3 ¶ 12). Plaintiffs object to this affidavit because the Defendant obtained it by *ex parte* communications with Dr. Richards; the Defendant drafted the entire affidavit; Dr. Richards made no changes to the affidavit; and Defendant told him the affidavit would prevent him from having to be deposed. (Doc. 58-3 pp. 47-50, Deposition of Dr. Richards).

Since learning of the connection between bisphosphonates, ONJ, and dental extractions, Dr. Richards now works closely with his patients' oral surgeons. (*Id.* at p. 62). He also notifies his patients that they need to let their oral health care professionals know they are on bisphosphonates. (*Id.* at p. 64). It is unclear exactly when Dr. Richards made this change to his general practice. (*Id.* at p. 62).

B. Facts relating to *Daubert* motions.

Plaintiffs have presented three treating physicians as expert witnesses and one retained expert. The three treating physicians are: Dr. Richards, Mrs. Monroe's oncologist; Dr. Patil, Mrs. Monroe's oral surgeon; and Dr. Huntress, Mrs. Monroe's dentist. The retained expert is Dr. Kraut, an oral and maxillofacial surgeon.

All of Mrs. Monroe's treating physicians disclaimed any specific causation expertise. Dr. Patil testified he would need to further review Mrs. Monroe's records to determine the cause of her ONJ, which he did not do. (Doc. 46-28 pp. 68-69, Deposition of Dr. Patil). Dr. Richards testified he had no opinion to a reasonable degree of scientific certainty as to what caused Mrs.

Monroe's ONJ. (Doc. 46-17 p. 45, Deposition of Dr. Richards). Dr. Huntress testified he did not feel qualified to offer an expert opinion as to what caused Mrs. Monroe's ONJ. (Doc. 47-1 p. 47, Deposition of Dr. Huntress). Further, he testified that he did not perform a differential diagnosis to determine the cause of Mrs. Monroe's ONJ. (*Id.* at 27-28).

Plaintiffs also introduced Dr. Richard Kraut as a specific causation expert. Dr. Kraut is board certified in oral medicine, oral and maxillofacial surgery, and dental anesthesia. (Doc. 50-2 Ex. 6 p. 1, Expert Report of Dr. Kraut). In addition, he has published two articles on bisphosphonates. (*Id.*) In 1988, following his discharge from the U.S. Army, Dr. Kraut became the Director of oral and maxillofacial surgery for Montefiore Medical Center/Albert Einstein College of Medicine, a position he still holds. (*Id.*) In addition, in 2003, he became the chairman of the Department of Dentistry of Montefiore Medical Center/Albert Einstein College of Medicine. (*Id.*) He is a Senior Section Editor of the *Journal of Implant Dentistry* and a reviewer for oral surgery, oral pathology, and the *Journal of Oral and Maxillofacial Surgery*. (*Id.*)

Dr. Kraut's expert report details a differential diagnosis where he concludes that bisphosphonate-related jaw necrosis is the correct diagnosis. (*Id.* at 4).

Dr. James Vogel also submitted an expert report as a general causation expert and an expert on the inadequacy of the warnings for the risks of Zometa. Neither party specifically relies on any part of

his expert report in their motions; however, a motion to exclude his expert report is before the Court.

Dr. Vogel's expert report states: "The risk for developing ONJ increases with the amount of bisphosphonate a patient takes. There is a dose response relationship." (Doc. 54-8 ¶ 22, Expert Report of Dr. James Vogel). This opinion cites to three studies on ONJ that found increased bisphosphonate use increased the risk of ONJ.

In addition, Dr. Vogel's report includes a section concluding the warnings given by Defendant were inadequate to warn the medical community of Zometa's risk of ONJ. (Doc. 54-8 p. 12, Dr. Vogel's Expert Report).

CONCLUSIONS

1. Can Mrs. Monroe's treating physicians testify to specific causation? No, but they can testify to their treatment of Mrs. Monroe.
2. Can Dr. Kraut testify to specific causation? Yes, because Dr. Kraut is qualified and used a proper methodology to reach his expert opinion.
3. Can Dr. Marx, Dr. Vogel, and Dr. Parisian testify as expert witnesses? This decision is reserved for a later time as it is not material to the resolution of the current summary judgment motions.
4. Should Defendant's motion for summary judgment be granted because Mrs. Monroe assumed the risk of ONJ? No, there are genuine issues of material fact on this issue.

5. Do the risks of Zometa outweigh the benefits under Ohio Revised Code 2307.75(A)? No. Defendant has presented evidence that the benefits of Zometa outweigh the risks and Plaintiffs have failed to present any evidence to the contrary. Because Plaintiffs design defect claim fails at the outset, the Court finds Ohio Revised Code 2307.75(D) and (F) inapplicable.
6. Should the Defendant's motion for summary judgment be granted on Plaintiffs inadequate warning claim because the warnings were adequate? No, Plaintiffs have presented expert evidence that the warnings were inadequate creating a genuine issue of material fact. Further, there is a genuine issue of material fact on whether the warning proximately caused Mrs. Monroe's injury.
7. Did Zometa fail to conform to any representation made by the Defendant? No, the Plaintiffs have failed to present any evidence from which a reasonable juror could conclude Novartis made an express representation.
8. Are punitive damages available? No, federal law preempts punitive damages.
9. Should Plaintiffs' loss of consortium claim survive Defendant's motion for summary judgment? Yes, because Plaintiffs' loss of consortium claim is derivative of their other claims it survives.

ANALYSIS

A. *Daubert* Motion relating to treating physicians and Dr. Kraut.

1. Treating physicians' expert testimony.

"Generally, a treating physician may provide expert testimony regarding a patient's illness, the appropriate diagnosis for that illness, and the cause of the illness." *Gass v. Marriott Hotel Servs., Inc.*, 558 F.3d 419, 426 (6th Cir. 2009). However, Mrs. Monroe's treating physicians must still satisfy *Daubert* standards to offer an expert opinion. *Id.* But there is a recognized difference between being able to diagnosis a condition and being able to determine the cause of a condition. *Id.*

The Court in *Gass* held that the District Court did not abuse its discretion when it held that the treating physicians could testify about their diagnosis and treatment of plaintiff but not about specific causation. *Id.* at 428. Similarly, the treating physicians here are experienced and qualified to testify about their diagnoses and treatments of Mrs. Monroe. But here, the treating physicians have all expressly stated they are unqualified to offer an opinion on specific causation, or that they do not have the facts required to conduct a reliable analysis to determine causation.

2. Dr. Kraut's expert testimony.

However, Dr. Kraut, Plaintiffs' retained expert, may testify as to the specific cause of Mrs. Monroe's ONJ. While, Defendant attacks Dr. Kraut's qualifications, Federal Rule of Evidence 702 expressly considers qualification based on experience. *Dickenson v. Cardiac & Thoracic Surgery of E. Tenn.*, 388 F.3d 976, 980 (6th Cir. 2004). Dr.

Kraut's long career in oral and maxillofacial surgery (and the fact that he is board certified), his positions as an editor or reviewer of peer journals, his positions at Albert Einstein College of Medicine, and his experience with ONJ all qualify him as an expert in this area.

Defendant also attacks Dr. Kraut's methodology. "Differential diagnosis is [t]he method by which a physician determines what disease process caused a patient's symptoms. The physician considers all relevant potential causes of the symptoms and then eliminates alternative causes based on a physical examination, clinical tests, and a thorough case history." *Best v. Lowe's Home Centers, Inc.*, 563 F.3d 171, 178 (6th Cir. 2009) (quotations omitted). "This court recognizes differential diagnosis as an appropriate method for making a determination of causation for an individual instance of disease." *Id.* (quotations omitted).

The Sixth Circuit has held that a differential diagnosis is reliable and admissible where the doctor "(1) objectively ascertains, to the extent possible, the nature of the patient's injury, . . . (2) 'rules in' one or more causes of the injury using a valid methodology, and (3) engages in standard diagnostic techniques by which doctors normally rule out alternative causes to reach a conclusion as to which cause is most likely." *Id.* at 179.

Dr. Kraut satisfied this standard with his differential diagnosis in his expert opinion. He states, after reviewing the appropriate professional literature and Mrs. Monroe's extensive medical records, that:

> When considering the possible diagnoses or etiology of this, one is left with a few classic entities that can

> cause such necrosis. Since there was no therapeutic radiation to the maxilla or mandible, osteoradionecrosis needs to be eliminated from the differential diagnosis. The fact that she was treated with hyperbaric oxygen, multiple debridements and still continued to have jaw necrosis is inconsistent with the behavior of osteomyelitis. In fact all of the provider's [sic] records that I have reviewed indicate that they believe that the patient had bisphosphonate related jaw necrosis. I concur with their findings based on the fact that she had multiple debridements and courses of antibiotics that failed to resolve until both the maxilla and mandible were resected.

(Doc. 50-2 Ex. 6, Dr. Kraut's Expert Report).

Defendant argues that this differential diagnosis is flawed and that Dr. Kraut failed to consider other possible causes of Mrs. Monroe's ONJ. However, this goes to the weight of Dr. Kraut's opinion, not its admissibility. *McCullock v. H.B. Fuller Co.*, 61 F.3d 1038, 1044 (2d Cir. 1995) ("Disputes as to the strength of his credentials, faults in his use of differential etiology as a methodology, or lack of textual authority for his opinion, go to the weight, not the admissibility, of his testimony.) (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 596, (1993) ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.")).

Thus, Dr. Kraut's expert opinion on specific causation is admitted because he is qualified and his methodology meets *Daubert's* standard for reliability.

3. Remaining experts' opinions.

Finally, Dr. Vogel's testimony about the dosage response relationship is admissible. Defendant argues that Dr. Vogel's alternative dosing schedule which consists of one dose every three

months after a patient has been on Zometa for two years should be excluded.[3] However, Defendant never argues that Dr. Vogel's opinion that the risk for developing ONJ increases the more bisphosphonate a patient takes is inadmissible. Defendant does not challenge this portion of Dr. Vogel's expert report, instead attacking his alternative dosing schedule and dental examination opinions.

The Court has a gatekeeping function, regardless of Defendant's challenge. Dr. Vogel is qualified. His report states he has been practicing in the field of hematology and medical oncology for thirty-five years and he is an Associate Professor at the Mount Sinai School of Medicine, Division of Hematology/Medical Oncology. (Doc. 54-8 ¶¶ 1-2). His conclusion is supported by at least three research reports, which he cites. Defendant does not challenge the accuracy or reliability of those reports. As such, Dr. Vogel is qualified and relies on a proper methodology for his conclusion as it relates to the risk for developing ONJ.

In addition, Dr. Vogel stated in his expert report: "In my opinion, the causal relationship between intravenous bisphosphonate drugs and ONJ was obscured by presenting a number of possibilities without focusing on the real problem." (Doc. 54-8 ¶ 39). Further, it is his opinion that the label is misleading because it begins by discussing ONJ then listing factors that are associated with just osteonecrosis and not osteonecrosis of the jaw. (*Id.* at ¶ 44). Dr.

[3] As stated above, the Court declines to resolve this motion at this time.

Vogel's expert report details why he believes Zometa's warnings were inadequate and this testimony is admissible.

B. Plaintiffs' claims for inadequate warning and loss of consortium survive. Plaintiffs' design defect and nonconformance with representation claims fail.

4. Whether Mrs. Monroe assumed the risk of ONJ is a question for the jury.

Defendant argues that Mrs. Monroe assumed the risk of ONJ and thus all of her claims fail. Ohio Revised Code § 2307.711(B)(2) states that if a plaintiff "expressly or impliedly assumed a risk and that the express or implied assumption of the risk was a direct and proximate cause of harm for which the claimant seeks to recover damages, the express or implied assumption of the risk is a complete bar to the recovery of those damages." "Thus, where a plaintiff knew of the danger a product posed and nonetheless voluntarily proceeded in his course of action, he may not recover." *Allen v. Indep. Concrete Pipe Co.*, No. 3:04-CV-7053, 2005 WL 3274679, at *2 (N.D. Ohio Dec. 2, 2005) (citing *Bowling v. Heil Co.*, 511 N.E.2d 373, 378 (Ohio 1987)).

Defendant argues that, because Mrs. Monroe signed a form listing "death" as a possible side effect for Zometa, she assumed the "lesser" risk of ONJ. Defendant also argues that Plaintiffs have presented no evidence that Mrs. Monroe was not warned of the risk of ONJ before starting Zometa. However, assumption of the risk is an affirmative defense which Defendant must prove; it is not the Plaintiffs' burden to disprove.

Defendant points to statements by Dr. Richards, Mrs. Monroe's treating physician, where he stated he began warning his patients shortly after learning of the risk of ONJ and "I would like to think

that we discussed ONJ. I would hope so. I think we probably did." (Doc. 58-3 pp. 24-25). This, however, does not affirmatively show that Mrs. Monroe either explicitly or implicitly assumed the risk of ONJ. This is a question of credibility for the trier of fact. Therefore, the defense of assumption of the risk is not applicable on the present record.

5. Plaintiffs' design defect claim.[4]

Plaintiffs fail to adequately support their design defect claim. A defective design claim arises under Ohio Revised Code § 2307.75. The OPLA provides that a product is defective in design "if, at the time it left the control of its manufacturer, the foreseeable risks associated with its design . . . exceeded the benefits associated with that design. . . ." Ohio Rev. Code Ann. § 2307.75(A) (West). However, a prescription drug "is not defective in design or formulation because some aspect of it is unavoidably unsafe, if the manufacturer of the ethical drug . . . provides adequate warning . . . concerning that unavoidably unsafe aspect." Ohio Rev. Code § 2307.75(D).

The statute also provides that a product is **not defective in design** if there was no "practical and technically feasible alternative design . . . that would have prevented the harm for which the claimant seeks to recover. . . ." Ohio Rev. Code § 2307.75(F). Although this subsection does not state that it is a plaintiff's burden to prove an alternative design, the Sixth Circuit has so held. *McGrath v. Gen. Motors Corp.*, 26 F. App'x 506, 510 (6th Cir. 2002) ("[Plaintiff]'s

[4] Plaintiffs are not pursuing a manufacturing defect claim.

argument that he is not required to provide such evidence is therefore without merit."); *Jacobs v. E.I. du Pont de Nemours & Co.*, 67 F.3d 1219, 1242 (6th Cir. 1995).

Dr. Richards, Mrs. Monroe's treating physician, testified that the benefits of Zometa outweighed the risks and that he would still prescribe the medication today. In addition, the FDA has approved Zometa, indicating that the benefits outweigh the risks. Defendant argues further that Plaintiffs have disclosed "no expert who will provide the necessary testimony establishing a feasible alternative design for Zometa." (Doc. 48-1 p. 13).

In Plaintiffs' response, their only argument is that "because the issue of dose and duration are contested, a design defect claim survives. Novartis either knew a lesser dose was efficacious or willfully avoided finding out for profit reasons." (Doc. 51 p. 33). This argument is almost identical to the argument the plaintiff in *Mathews* and *Sheffer* made. In those cases, the Court found that because the plaintiff failed to expand on its dose and duration argument, no reasonable jury could find in favor of plaintiff. *Mathews*, No. 3:12-CV-314, 2013 WL 5780415, at *7; *Sheffer*, No. 3:12-CV-238, 2013 WL 5276558, at *8-9. Further, as in *Mathews* and *Sheffer*, the Court has no independent obligation to search the record for expert evidence and may choose to consider only the evidence cited by the parties. Fed. R. Civ. P. 56(c)(3).

Defendant has put forth expert testimony that the benefits of Zometa outweigh the risks. Because Plaintiffs fail to present evidence that Zometa's risks outweighed its benefits, Zometa is not

defective in design under Ohio Revised Code 2307.75(A) as a matter of law.

6. Plaintiffs' inadequate warning claim.

A product is defective due to inadequate warning under the OPLA when:

> (a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;
>
> (b) The manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

Ohio Rev. Code § 2307.76.

Courts have restated the above statutory language as requiring three elements "each of which must be satisfied: (1) a duty to warn against reasonably foreseeable risks; (2) breach of this duty; and (3) an injury that is proximately caused by the breach." *Graham v. Am. Cyanamid Co.*, 350 F.3d 496, 514 (6th Cir. 2003).

There is a genuine issue of material fact on whether the warnings here were adequate. Dr. Vogel's expert opinion challenges the adequacy of the warnings to the medical community. Further, the MDL Court held that, at least for Wave I cases, there was an issue of fact on the adequacy of the warning. *In re Aredia and Zometa Prods. Liability Litigation,* No. 3:06-md-1760, Docs. # 2766, 2767 (M.D. Tenn. Aug. 13 2009). It found genuine issues of material fact on what Defendant knew and when, whether other risk factors for ONJ exist, and whether Defendant adequately informed physicians of the known or

knowable risks. *Id.* Again, this case is similar to *Mathews* and *Sheffer*, both of which found a question of fact on breach of duty based on the MDL Court's holdings. The same conclusion is reached here.

Defendant argues that even if there is a question of fact on the adequacy of the warning, Plaintiffs' claim fails because of a lack of proximate cause. To establish proximate cause a plaintiff must show "(1) whether [the] lack of adequate warnings contributed to plaintiff's use of the product and (2) whether use of the product constituted a proximate cause of the plaintiff's injury." *Miller v. ALZA Corp.*, 759 F. Supp. 2d 929, 936 (S.D. Ohio 2010); *see also Seley v. G. D. Searle & Co.*, 423 N.E.2d 831, 838 (Ohio 1981).

The Ohio Supreme Court in *Seley* looked to the Restatement of Torts 2d, Section 402A comment j, which establishes a presumption that if an adequate warning is given it will be read and heeded, which benefits the manufacturer. *Seley*, 423 N.E.2d at 838. However, where an inadequate warning is given, the presumption favors the plaintiff. That is, "the failure to adequately warn was a proximate cause of the plaintiff's ingestion of the drug." *Id.*

Whether the lack of adequate warnings contributed to a plaintiff's use of the product is established by the presumption provided when an inadequate warning is given. However, a defendant can rebut this presumption by showing that "an adequate warning would have made no difference in the physician's decision as to whether to prescribe a drug or as to whether to monitor the patient thereafter."

Id. If rebutted, "the required element of proximate cause between the warning and ingestion of the drug is lacking." *Id.* at 839.

Defendant argues it has overcome this plaintiff-friendly presumption because Dr. Richards, Mrs. Monroe's treating physician, stated in his affidavit: "If a patient presented to me today just as Mrs. Monroe presented to me in May of 2005, I would still recommend Zometa to that patient because the benefits of Zometa treatment outweigh the risk of developing ONJ." (Doc. 48-3 ¶ 12, Declaration of Dr. Richards). Thus, Defendant argues, there is no evidence that "a different ONJ warning would have made a material difference in Mrs. Monroe's treatment and thereby prevented her alleged injury." (Doc. 48-1 p. 11, Defendant's Motion for Summary Judgment.)

There are two grounds that would allow Plaintiffs to satisfy their proximate cause burden: (a) that Defendant's argument fails to account for monitoring the patient, and (b) that whether Dr. Richards would or would not prescribe Zometa again is a question of credibility for the jury to decide.

a. Whether Dr. Richards would have monitored Mrs. Monroe differently had he been adequately warned, and whether that would have reduced her risk of injury.

Plaintiffs argue that Dr. Richards's testimony fails to show that an adequate warning would have made no difference in the physician's decision "as to whether to monitor the patient thereafter" and thus, Defendant has failed to rebut the presumption. Plaintiffs argue Dr. Richards changed his monitoring habits of his patients in response to a Mayo Clinic publication when he began generally reducing the frequency of administration of Zometa to his patients. (Doc. 58-3 pp.

35-36, Deposition of Dr. Richards). Around this time, he also reduced the frequency Mrs. Monroe's Zometa infusions. (*Id.*) Because of this change, Plaintiffs argue that Defendant has failed to rebut the presumption that the inadequate warning caused her to ingest the drug.

"[W]here the treating physician unequivocally testifies that s/he would have prescribed the subject drug despite adequate warnings, judgment as a matter of law is appropriate." *Miller v. ALZA Corp.*, 759 F. Supp. 2d 929, 936 (S.D. Ohio 2010). In *Miller*, the treating physician testified that he would have prescribed the drug regardless of a different warning and that he **would not have monitored the patient any differently**. *Id.* at 396-97. Unlike in *Miller*, however, Dr. Richards testified that he has changed frequency of dosage based on additional information.[5] This would allow for the inference that, had Dr. Richards been adequately warned, he would have changed his practice earlier, which may have prevented Mrs. Monroe's injury.

This theory, however, would change step two in the proximate cause analysis. The first step is: did the inadequate warning cause the plaintiff to ingest the drug. Here, it appears an adequate warning may have caused Mrs. Monroe to take less frequent doses of the drug, but it would not have stopped her from ingesting it completely. Step two requires that the drug proximately caused injury to the

[5] Plaintiffs also argue that Dr. Richards has changed his monitoring by providing pre-treatment dental screenings, along with closer coordination with oral surgeons. However, because Mrs. Monroe developed "spontaneous ONJ," these changes would have had no effect on her injury and thus this consideration is not relevant to the proximate cause inquiry.

Plaintiff. Dr. Kraut, Plaintiffs' retained expert, testified that Zometa caused Mrs. Monroe's ONJ.

If the drug caused the injury, it is easy to see how not ingesting a drug at all would also satisfy step two. That is, not taking the drug means the plaintiff would not have been injured. However, to say that taking less of the drug would not have caused the injury would require expert testimony because that determination is beyond the ken of the average juror.

Dr. James Vogel's expert report states, "The risk for developing ONJ increases with the amount of bisphosphonate a patient takes. There is a dose response relationship." (Doc. 54-8 ¶ 22, Expert Report of Dr. James Vogel). Because this testimony is admissible, it supports Plaintiffs' argument that the inadequate warning caused *increased* ingestion of Zometa which in turn increased Mrs. Monroe's risk of developing ONJ. Thus, at minimum, the inadequate warning caused an increased risk of developing ONJ. Therefore, the Plaintiffs' inadequate warning claim survives.

b. There is a question of credibility whether Dr. Richards would have prescribed Zometa had he been given an adequate warning.

Dr. Richards testified in his affidavit that if a patient presented to him today as Mrs. Monroe did he would still prescribe Zometa because the risk outweighs the benefit. (Doc. 48-3 ¶ 12). He reaffirmed this in his deposition. (Doc. 58-3 p. 67). However, a question of credibility exists whether Dr. Richards would actually take this course of action.

In *Seley*, the Court found that because the patient did not tell her doctor about her history of hypertension, even if an adequate warning was provided, her doctor would have had no reason to warn her. Thus, the presumption favoring the plaintiff was rebutted. But in *Williams v. Lederle Laboratories*, 591 F. Supp. 381, 386 (S.D. Ohio 1984), the Court found that an issue of credibility existed. The Court there said the test "is whether the evidence affirmatively establishes that a physician would not have responded differently had he received an adequate warning." *Id.*

There, the treating physician testified that, despite his current knowledge of the risk of the medication at issue and his knowledge of the specific risk of injury to the plaintiff, he still does not warn of the risk. The Court concluded "that it is for the jury to determine whether the presence of an adequate warning would have made no difference in Dr. Furlong's decision" because what the treating physician "might or might not have done involves to some degree his credibility." *Williams*, 591 F. Supp. at 387.

Here, Plaintiffs point out that Dr. Richards's affidavit was prepared by the Defendant and that Dr. Richards made no changes to it before signing it. Further, Dr. Richards has changed his practice since new warnings were provided. He now warns patients of the risk of ONJ (which he may or may not have done in Mrs. Monroe's case), he reduces the frequency of dosage for some patients based on the Mayo Clinic study (possibly including Mrs. Monroe), and he works closely with patients' dental providers. This is in stark contrast to the doctor in *Miller*.

Thus, it is a matter of credibility for the jury to determine whether Dr. Richards, given an adequate warning, would still have prescribed Zometa to Mrs. Monroe, despite his affidavit stating otherwise. It is similarly a matter of credibility whether he would have exercised more caution in monitoring Mrs. Monroe.

7. Plaintiffs' nonconformance with representation claim under OPLA § 2307.77

"A product is defective if it did not conform, when it left the control of its manufacturer, to a representation made by that manufacturer. A product may be defective because it did not conform to a representation even though its manufacturer did not act fraudulently, recklessly, or negligently in making the representation." Ohio Rev. Code Ann. § 2307.77 (West). A "representation" is defined as an "express representation of a material fact concerning the character, quality, or safety of a product." Ohio Rev. Code Ann. § 2307.71(A)(14)(West); *see Mathews v. Novartis Pharm. Corp.*, No. 3:12-CV-314, 2013 WL 5780415, at *12 (S.D. Ohio Oct. 25, 2013).

A plaintiff must satisfy four elements to recover for a nonconformance with representation claim under the OPLA:

> 1) that the manufacturer made a representation as to a material fact concerning the character or quality of the manufacturer's product;
> 2) that the product did not conform to that representation;
> 3) that the plaintiff justifiably relied on that representation; and
> 4) that the plaintiff's reliance on the representation was the direct and proximate cause of the plaintiff's injuries.

Mathews, 2013 WL 5780415, at *12 (quoting *Gawloski v. Miller Brewing Co.*, 644 N.E.2d 731, 734 (Ohio Ct. App. 1994)).

A general warranty of "good, safe and merchantable quality" was held to be insufficient to constitute an express representation under Ohio Revised Code § 2307.77. *Saraney v. TAP Pharm. Products, Inc.*, 104 CV 02026, 2007 WL 148845, at *8 (N.D. Ohio Jan. 16, 2007) ("The [Plaintiffs'] bare allegation, contained in their complaint, that [Defendant] generally warranted Lupron of "good, safe and merchantable quality" is insufficient to prove the express representation necessary to meet the standards laid down in O.R.C. § 2307.77.").

Plaintiffs' amended complaint adds additional representations beyond the "good, safe and merchantable," but Plaintiffs fail to establish an express representation was made to either Mrs. Monroe or her treating physician. (Doc. 52-1 ¶¶ 32-35). Plaintiffs argue that Defendant's prior motions for summary judgment in similar cases, where the amended complaint's allegations were made, have been denied. *Bowles v. Novartis Pharm. Corp.*, No. 3:12-CV-145, 2013 WL 5297257, *14 (S.D. Ohio Sept. 19, 2013); *Sheffer v. Novartis Pharm. Corp.*, No. 3:12-CV-238, 2013 WL 5276558, *15 (S.D. Ohio Sept. 18, 2013). But, where the amended complaint's allegations were not made, summary judgment was granted. *Mathews v. Novartis Pharm. Corp.*, No. 3:12-CV-314, 2013 WL 5780415, *13 (S.D. Ohio Oct. 25, 2013).

This Court granted Plaintiffs' motion to amend their complaint. (Doc. 63). In the *Bowles* and *Sheffer* cases, Defendant failed to amend its summary judgment motions to respond to the amended complaint and the new allegations contained therein. Defendant was not granted summary judgment in those cases because it failed to support its initial burden of showing a lack of record evidence to support the

allegations. Here, however, Defendant challenged these additional express representations in its newly filed motion for summary judgment. (Doc. 68-1).

Plaintiffs' specific allegations are that Zometa expressly warranted that it strengthened bones when, in fact, it weakened jaw bones; that its side effects were "mild and transient" when Zometa actually caused serious, permanent BRONJ injuries; that Zometa did not cause BRONJ; and that continued dosing with Zometa after two years was effective. (Doc. 64 ¶¶ 32-35).

Defendant challenges these representations stating that there is "no evidence that NPC made 'an express representation of a material fact concerning the character, quality, or safety of a product' to either Mrs. Monroe or Dr. Richards." (Doc. 68-1 p. 9, Defendant's motion for summary judgment). Plaintiffs respond but fail to point to any evidence that supports their allegations. (Doc. 73 p. 4).

Plaintiffs state, without citation to the record, that the drug warranted to strengthen bones, not weaken jaw bones. The Court has no independent obligation to search the record for evidentiary support. Fed. R. Civ. P. 56(c)(3). As such, this express representation claim fails.

Plaintiffs also state that Defendant advertised Zometa's side effects as "mild and transient." However, this statement points to a portion of the Zometa product label discussing "Hypercalcemia of Malignancy," not ONJ or any injury suffered by Mrs. Monroe. This is insufficient to show an express warranty made by Novartis to either

Dr. Richards or Mrs. Monroe that **all** side effects were "mild and transient."

Lastly, Plaintiffs assert that a Novartis salesman's report, which shows the salesman met with Dr. Richards and states, "Zometa continuing, onj not a problem," is enough to infer that an express representation was made to Dr. Richards that ONJ was not caused by Zometa. A reasonable juror, from this information alone, could not reasonably infer an express representation was made by a Novartis salesman to Dr. Richards that ONJ was not a side effect of Zometa. This inference goes too far and invites speculation.

Thus, Plaintiffs have failed to cite to any record evidence supporting their express warranty allegations. Because Plaintiffs have failed to point to any evidence from which a reasonable jury could infer an express warranty was made to Mrs. Monroe or Dr. Richards, their nonconformance with representation claim fails.

8. Punitive damages are preempted and are not available.

In determining the availability of punitive damages, there is a threshold conflict of law issue. This case was transferred from the District of Columbia and as such, its choice-of-law rules apply. *Ferens v. John Deere Co.*, 494 U.S. 516, 523 (1990) ("[A] transferee forum [is required] to apply the law of the transferor court, regardless of who initiate[d] the transfer. A transfer under § 1404(a), in other words, does not change the law applicable to a diversity case.").

"First, the Court must determine which States have an interest in the controversy at hand." *Keene Corp. v. Ins. Co. of N. Am.*, 597 F.

Supp. 934, 938 (D.D.C. 1984). Next, the Court must determine if there is a conflict of laws between those states with an interest. *See Estate of Doe v. Islamic Republic of Iran*, 808 F. Supp. 2d 1, 20 (D.D.C. 2011). However, "[a] conflict of laws does not exist when the laws of the different jurisdictions are identical or would produce the identical result on the facts presented." *USA Waste of Maryland, Inc. v. Love*, 954 A.2d 1027, 1032 (D.C. 2008). In that case, a choice of law analysis is not required.

Punitive damages are not allowed under either Ohio or New Jersey law. First, Ohio Revised Code § 2307.80(C)(1)(a) precludes punitive damages when the alleged drug "was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the federal food and drug administration under the 'Federal Food, Drug, and Cosmetic Act.'" But an exception exists if the plaintiff can show by a preponderance of the evidence "that the manufacturer fraudulently and in violation of applicable regulations of the food and drug administration withheld from the food and drug administration information known to be material and relevant to the harm that the claimant allegedly suffered or misrepresented to the food and drug administration information of that type." Ohio Rev. Code Ann. § 2307.80 (West).

This exception has been further abrogated by both the Supreme Court of the United States and the Sixth Circuit. The Supreme Court held that "the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001).

The Sixth Circuit, looking at Michigan law with a framework similar to Ohio, found that the difference between a common law claim of fraud on the FDA (as discussed in *Buckman*) and immunity under Michigan law unless fraud could be shown was "immaterial in light of *Buckman*." *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004). Instead, the Sixth Circuit held that "**state tort remedies** requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims." *Id.* (emphasis added). The Sixth Circuit has extended this rule, holding that "claims that the manufacturer misrepresented or withheld information about a drug from the FDA after the FDA had approved it" were also preempted. *Marsh v. Genentech, Inc.*, 693 F.3d 546, 551 (6th Cir. 2012). One District Court found that "a punitive-damages claim for an FDA-approved drug is allowed under Ohio law *only if* the FDA has made a finding of either fraud or misrepresentation." *In re Gadolinium-Based Contrast Agents Products Liab. Litig.*, MDL No. 1909, 2013 WL 587655, at *14 (N.D. Ohio Feb. 13, 2013). Because there has been no finding of fraud by the FDA here, no punitive damages claim is permissible.

New Jersey similarly bars punitive damages and Plaintiffs' failure to contest this point means it was conceded. *See Rowe v. Hoffman-La Roche, Inc.*, 917 A.2d 767, 774 (N.J. 2007)("The Legislature also provides in the NJPLA that FDA approval of prescription drugs conclusively prohibits an award of punitive damages in products liability actions"). There is thus no true conflict and no conflict of law analysis is required because New Jersey and Ohio do not allow a

punitive damages claim under these facts. Therefore, federal law preempts any punitive damages claim in this case.

9. Plaintiffs' loss of consortium claim survives.

Plaintiffs' loss of consortium claim is derivative of their other claims. That is, it can only exist if one of the other underlying causes of action exists. Because the inadequate warning claim survives summary judgment, the loss of consortium claim does as well.

Therefore, having reviewed this matter and heard oral argument, and the Court being otherwise sufficiently advised,

IT IS ORDERED that Defendant's Motion to Exclude (Doc. 45) is **GRANTED IN PART** (barring the treating physicians from testifying as to specific causation) and **DENIED IN PART** (allowing Dr. Kraut to testify).

Defendant's Motion for Summary Judgment (Doc. 48) is **GRANTED IN PART** (the design defect claim is dismissed and punitive damages are not available) and **DENIED IN PART** (the failure to warn and loss of consortium claims survive).

Defendant's Motion for Summary Judgment (Doc. 68) on Plaintiffs' Nonconformance with Representation claim is **GRANTED**.

Defendant's Motion to Exclude Professor Wayne Ray (Doc. 55) is **DENIED AS MOOT** based on Plaintiffs withdrawal of Prof. Ray as an expert. (Doc. 62).

This 10th day of July, 2014.

Signed By:

William O. Bertelsman WOB

United States District Judge